The Usage of Biomedical Treatments for Children with Autism: A Descriptive Study

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ABSTRACT:

The purpose of this study was to determine if the parents of children with autism sought biomedical interventions (dietary supplements and special diets) following the positive diagnosis of their child. Approval was obtained from the Ohio State University (OSU) Institutional Review Board. Names and phone numbers of children who had a positive diagnosis for an Autism Spectrum disorder, including classic autism, Asperger's, and Persuasive Developmental Disability- Not Otherwise Specified (PDD-NOS) were obtained from three OSU diagnostic clinics where these patients had been seen over the past 1-25 months. Fifty-five families were identified from the database and contacted by phone regarding biomedical interventions explored since diagnosis. Of these 55, 21 were successfully interviewed, 2 opted not to be interviewed, 20 were left messages and a researcher contact phone number, and 13 had disconnected lines. Of the 21 who responded, 12 (57%) used a dietary supplement. Of these 12, 5 used a multivitamin only, and 7 used one or more of the following: fish oil, folic acid and vitamin B-12 (pill, injection and topical crème), Co-enzyme Q-10, riboflavin, vitamin A, calcium, vitamin D, probiotics, magnesium, and fiber. Number of supplements used was compared with months since diagnosis. Of these same 21 parent respondents, 8 (38%) have tried special diets, 6 tried the Gluten Free Casein Free diet (GFCF), and 4 are still following it. Sixteen respondents consulted with practitioners (allopathic or alternative); three with a registered dietitian, three with a pediatrician , four nonconventional sources such as a Defeat Autism Now Doctor and New Hope Detoxification Doctor , three with "other sources" (a special diet from Helping Hands Education and Therapy Center and a food coach). Other resources consulted included the internet (61%). Educational Intervention plans include the development of Nutrition Interventions and Therapies for Autism (NITA) as a service to the ever-growing autism community.

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Problem Statement

For decades, autism was believed to occur in 4 to 5 per 10,000 children (CDC). However, in 2007, CDC's Autism and Developmental Disabilities Monitoring found that 1 in 150 eight-year-old children have an autism spectrum disorder (ASD). This data was taken from many areas across the United States and is a national problem. This study takes place through the Nisonger Center at Ohio State University, and over the last year 90-95% of the children referred to the Nisonger Autism center were diagnosed with a type of ASD.

Autism is often referred to as ASD because there are different types that tend to fall onto a spectrum of levels of functioning. Yale medical center defines a few of these syndromes on the spectrum. In Asperger's syndrome (AS), patients have deficits in social interaction and unusual response to environment but differ from classical autism because cognitive and communicative skills are in a near normal range. Another syndrome on the spectrum is Pervasive Developmental Disorder not otherwise specified (PDD-NOS). This falls in a "subthreshold" category and no specific guidelines are provided. Deficits in peer relations and unusual sensitivities exist, however social skills in a normal range. In childhood disintegrative disorder (CDD) children develop normally then after a prolonged period (2 to 4 years old) begin to show symptoms of autism (Yale School of Medicine, 2008). In terms of level of functioning measures, a study in the Journal of the American Academy of Child & Adolescent Psychiatry discovered that children with PDD-NOS had scores that were between those of the children with autism and those of the children with AS (Walker, 2004).

One study states "Understandably, few disorders can pose a greater threat to the well-being of families than autism" (Seltzer, Krauss, Orsmond, & Vestal, 2001). Having a child be diagnosed with autism can be an extremely difficult time for parents. Studies have found parents become stressed, depressed and sometimes even angry. One stressor described in described in

"Living in a World of Our Own: The Experience of Parents Who Have a Child with Autism" is the intense treatment that requires a combination of strategies. Another stressor from that article is that parents must do all they can. Parents feel they must try anything and everything to help their child develop to his or her full potential (Woodgate et al, 2008). One of these strategies parents can try is nutritional interventions that include changes in diet and nutritional supplements. A survey on supplemental interventions found that parents on average used seven supplements at a time (Smith, 2000). One parent even uses fourty seven different supplements (Green, 2006).

These nutritional interventions are referred to as Biologically-based therapies and Biomedical therapies interchangeably. These nutritional modifications seek to ameliorate symptoms that children that have autism often face such as chronic constipation, diarrhea, abdominal pain and GERD. These gastrointestinal symptoms may lead to "tantrums" from the child as a way to express his or her discomfort. These biomedical therapies include a gluten free-casein free diet because gluten and casein can be hard to digest. Anti-fungals are used to detoxify the bowel. Vitamin B-6 and magnesium and Omega-3 are used to treat nutrient defiencies. Vitamin b-12, folic acid, dimethylglycine and trymethylglycine are used to treat metabolic abnormalities. This study is based on the problem that these special diets and nutritional supplements are being used as interventions and therapies for children with ASD without proven safety and efficacy.

Literature Review

One common nutritional intervention is a Gluten-Free, Casein-Free (GFCF) diet. It is theorized that if a child cannot properly digest gluten and casein, the proteins cause an opioid-like effects on the central nervous system. However, what most parents probably do not know is there has been a lack of evidence-based research conducted with this diet. The most well-designed

research to date was done in 2002 by Knivsberg, Reichelt et all. This trial was small and included only 20 subjects, 10 in the treatment group 10 in the placebo group. The trial lasted 12 months and the results were measured using the Danish instrument for measuring autistic traits. The results were positive; social contact increased in 10 of the children and ritualized behaviors decreased in 8. While there is this one positive clinical trial for the GFCF diet, most of the evidence is anecdotal. A simple change in diet may seem safe, but it does have its risks. A study that was recently published in Journal of Autism and Developmental Disorders, finds that bone densities in 5 and 6 year old boys with autism were significantly thinner than the control group of boys without autism. This difference increases by age 6 and 7. The researchers hypothesized that this was due to a lack of variation in the boys' diet, lack of vitamin D, digestive problems and diets that exclude casein (Hediger, 2008). Dairy products that are excluded from a CFGF diet are a great source of calcium and vitamin D.

Dysbiosis is believed to be another cause of GI discomfort. A study presented at a "Defeat Autism Now" conference showed that out of 80 children with ASD and GI symptoms, 61% had abnormal gram negative endotoxin- producing bacteria, 55% had overgrowth of Staph aureus and 95% had an overgrowth of Escherichia coli (Rosseneu, 2003). However this study found no abnormal amounts to yeast noted. Despite a lack of evidence for presence of yeast, many children are being treated with antifungal as part of a bowel detoxification. Many antifungal medications are known to cause a "wide range of liver injury from a mild hepatocellular-cholestatic injury pattern to acute/subacute liver failure" (Perveze et al, 2006).

Many biomedical treatments address nutrient deficiency. A popular nutrient deficiency of current research is a combination of vitamin B6 and Magnesium. Out of the four studies found with treatments using the vitamin B6 and Magnesium combo, three showed no effects and one showed significant results (Kuriyama, 2002; Tolbert, 1993; Findling, 1997). Mousain-Bosc et al did a study with 33 children with PDD on 6 mg/kg/day Mg and .6 mg/kg/day Vit B6 for 8 months. 60% of the subjects improved in social interaction, communication and stereotyped

behavior. The potential risks with this treatment is that high doses of B6 can cause nerve damage and high doses of magnesium can cause reduced heart rate and weakened reflexes (Herbert et al, 2002).

Supplementing omega-3 is another treatment aimed at treating nutritional deficiency. The research with this supplement is contradictory. Two studies show significant improvement in behavior (Patrick et al, 2005 and Amminger et al, 2007); however the latest study, presented in 2008 at the Pediatric Academic Societies annual meeting shows no improvement. The potential risk here is that fish oil is an anticoagulant which can lead to problems with surgery and large cuts.

Melatonin supplementation has been suggested to help children with ASD sleep. A randomized controlled trial showed significant reduction in sleep latency and increased sleep time (Garstang et al, 2006). However, this is also possibly unsafe in children because of its affects on gonadal development.

Dimethylglycine (DMG) and Trimethylgylcine anhydrous (TMG) is used to treat metabolic abnormalities. A study by James et al. shows that children with autism have a metabolic imbalance when compared to the control group. This imbalance is consistent with "impaired capacity for methylation and increased oxidative stress "(James et al). DMG is involved in the methylation pathway and adding DMG to a child's diet would help normalize this balance. A double blind, placebo controlled study done in 2001 showed no difference in behavior between the placebo and DMG groups. TMG and DMG can be used to help Vitamin B12 deficiencies but it is too early to tell effectiveness. No studies to date have been done on the safety of TMG and DMG.

Vitamin B-12 and Folic acid are recommended for children with autism. However, even something as harmless as vitamin supplements can be potentially unsafe for children. A case study was done on a three year old boy with ASD who was hospitalized with symptoms of vomiting ceghalgias, fever and cutaneus abnormalities. These symptoms were due to

hypercalcemia that was caused by the biomedical treatment the boy was on for autism that included 100 000UI/d during three months and then 150 000UI/d the three following months of vitamin A (Kimmoun et al, 2007).

To add to the risk of these interventions, supplements are not regulated as drugs by the FDA, they are regulated as food. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), "the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed" (FDA, 1994). The FDA does have some responsibilities after the drug is on the market. These are to take action against unsafe dietary product and make sure product information is truthful. Generally, manufacturers do not need to register their products with FDA nor get FDA approval before producing or selling dietary supplements.

According to Herbert et al, "families are often persuaded to try methods that are highly unorthodox and scientifically suspect." Even when well designed studies have been done, the results tend to be contradictory. Many treatments also seem to carry risks, and even though most of these biomedical treatments can be bought over the counter, they aren't even regulated. Add in the other stressors a parent of a child with autism faces and it is easy to see how a parent could become overwhelmed. To add to the stress on the parents, children with ASD are very picky eaters and resisted trying new foods (Lockner et al, 2008). It is challenging for parents to get these picky eaters to eat an altered diet like the gluten free casein free diet. Despite these stressors, it is very exciting that there are many possible treatments out there for some of the symptoms of autism. And with parents "try anything they can" attitude, it is easy to see why these treatments are popular.

Research Questions

1) Since their child's diagnosis with ASD at Nisonger center, have these parents investigated biomedical treatments? Have the parents implemented any of these treatments?
2) Which biomedical treatments have they used?
3) What sources of information did the parents use?
    a. Ho: Those who do pursue these treatments have not consulted with a registered dietitian.

Methods

The sample population comprised of the 55 families of children who have been diagnosed at Ohio State University's Nisonger center from October 1, 2007 to September 30, 2008. The inclusion factor is the children must have had a positive diagnosis of autism on the spectrum according to DSM 4 criteria.

This study is a combination of a retrospective look at the charts of the children who have visited Nisonger's Autism lab and a prospective telephone survey with the parents of these children. The retrospective data that was collected from the chart include date of diagnosis, demographics and information about the family. Telephone segment queried the parents regarding their consideration and implementation of special diets or dietary or herbal supplements as well as where they received information on these nutritional alterations. A review of the literature has found no questionnaire that has been tested for validity or reliability. Therefore the telephone script has been written and revised with a qualitative researcher and reviewed for content validity. A phone interview is being used instead of a paper or internet survey because parents of children that have been diagnosed with ASD are very busy and previous studies

performed by a consulting registered dietitian using paper or internet surveys showed low response rate. Please see appendix A-C for telephone and verbal consent scripts.

Qualitative data was analyzed for central themes. Data was then summarized using descriptive statistics such as percentages and frequency counts. These data will be used for making further recommendations for nutrition interventions therapies for children with autism (NITA).

Results

Names and phone numbers of children who had a positive diagnosis for Autism Spectrum disorders, including classic autism, Asperger's Syndrome, and Persuasive Developmental Disability- Not Otherwise Specified (PDD-NOS) were obtained from three OSU clinics where these patients were seen over the past 1-25 months. Fifty-five (55) families were identified from the database and contacted by phone regarding biomedical interventions (the use of dietary and herbal supplements) explored and or employed since diagnosis. Of these fifty-five, 21 were successfully interviewed, 2 opted not to be interviewed, 20 were left messages and a researcher contact phone number, and 13 had disconnected lines.

One participant decided not to disclose this information about her son so the following demographics are derived from the remaining twenty (20) families. Twelve participants were diagnosed with Autism, 5 with PDD-NOS, 2 with PDD and 1 with Asperger's. The age range of participants was 2-8; 5 children were ages 2-3, 6 children ages 4-5, 6 children ages 6-7 and 2 children 8 years old or older. Most of the families interviewed had a child diagnosed within the last year with the distribution as follows: diagnosed in the last 6 months- 7 children; children diagnosed within the 7-12 months -

8; diagnosed within 13-17 months, 2 children; >18 or more months since diagnosis - 3 children.

Biomedical interventions are analyzed in this study as 2 separate categories, dietary supplements and special diets. Of the 21 families interviewed, 12 used supplements. Eight families only used one supplement. Most of these eight families used multivitamin only (6), one used fish oil and one specifically stated they used Omega-3 fatty acids. Four families used 2 or more supplements. The list of supplement use among these four families use was as follows: multivitamin(3), fish oil (3), probiotics(2), Folic Acid with B-12(1), Co-enzyme Q-10 (COQ 10)(1), B-2(1), Vitamin A(1), B12 topical cream(1), calcium with vitamin D(1), liquid calcium and magnesium(1), cod liver oil(1), vitamin and mineral powder(1), B-12 shots(1), chewable fiber (1), vitamin C (1).

The study revealed that most of the parents interviewed had considered following a special diet or modifying diet in some way. About half the parents were currently considering diet change but had not implemented it (10). Eight parents interviewed were currently using diet special diet for an intervention. The Gluten- Free, Casein- Free diet was the most popular with 6 families that have tried special diets. Of those, 4 were still using the diet and the others have stopped due to its difficulty, the child's need to fit in socially, or lack of perceived effectiveness. The 2 other diets used were a low fat diet with the help of Bureau for Children with Medical Handicaps (BCMH), and the Helping Hands Education and Therapy Center diet (Figure 1). With the Helping Hands diet, a coordinator at this special school for autistic kids feeds the child a healthy breakfast and lunch and the mom feeds the child a healthy dinner. If the son eats something he doesn't

like, he is rewarded with a bite of something he does. The child of the family interviewed did not eat for two days but now eats a healthy diet.

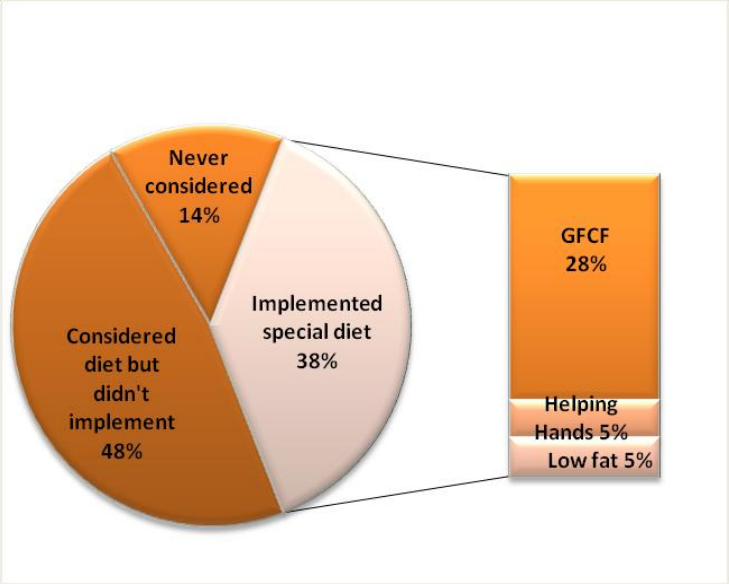

Figure 1-The Use of Special Diets by Children with Autism

The families were asked about what sources they consulted to obtain information regarding biomedical interventions. “Sources sought” were classified in two separate categories: practitioners and non-practitioners (referred to as other sources for this study). Fifteen families consulted a practitioner about biomedical interventions. Of these, 3 consulted a Registered Dietitian, 3 consulted a pediatrician, 4 consulted a nonconventional practitioner and 3 consulted an ‘other’ practitioner (Figure 2). Non conventional practitioners are comprised of “ Defeat Autism Now” (DAN) doctors and a “ New Hope detoxification doctor”. ‘Other’ practitioners’ input sought found in this study were from that of a food coach, a BCMH workshop and a Helping Hands case manager.

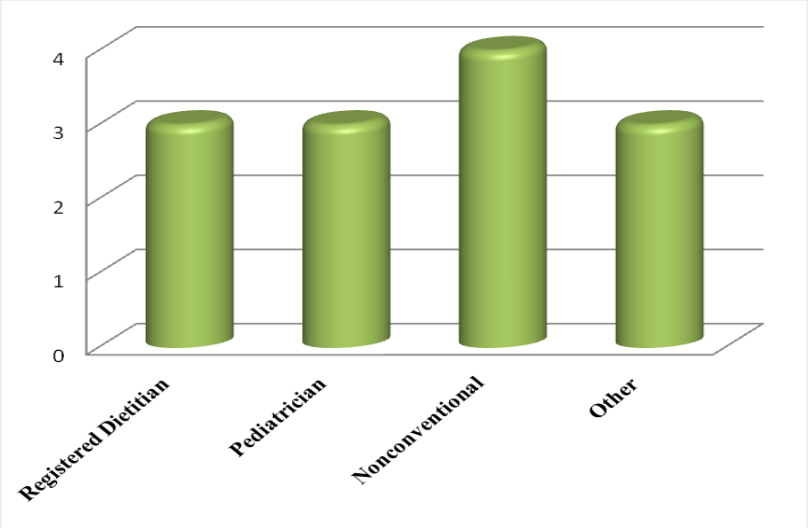

Figure 2- Allopathic and Alternative Practitioners

Several non-practitioners, or other sources, were also used by families to obtain information about biomedical treatments. The Internet was the most popular non-practitioner source sought (61%) followed by books, especially that by Jenny McCarthy: Healing and Preventing Autism: A Complete Guide. Families also consulted other parents of children with ASD, friends, families, and teachers. While not cited directly as a source, Occupational Therapists seem to have an influence on treatments parents choose. Of the 7 families who sought alternative or 'other' practitioners, 2 were recommended by the child's occupational therapist (the New Hope detoxification doctor and the food coach). Of the internet sites, autismspeaks.com was the most popular. See Table 1 for the distribution of parents who consulted these sources.

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Other Sources Sought (N = 21)	Count(%)
Internet	13 (61.9%)
Books	7 (23.8%)
Jenny McCarthy's Book	5 (23.8%)
Other Parents of Children with ASD	4 (19%)
School and Teachers	3 (14.3%)
Observe Children with ASD	2 (9.5%)
Friends and Family	2 (9.5%)

Table 1- Consultation of Other sources for Diet and Biomedical Treatments

The number of supplements used by each family studied in terms of months since diagnosis. Of the families with a child diagnosed in the last 6 months, 5.7% used 0 supplements, 0% used 1 supplement and 43% used 2 or more. Of the families with a child diagnosed 7-12 months ago, 37.5% used 0 supplements, 37.5% used 1 supplement and 25% used 2 or more. Of the families with a child diagnosed in the past 13-18 months ago, 50% used 0 supplements, 50% used 1 supplement and 0% used 2 or more. Of the families with a child diagnosed more than 18 months ago, 66.6% used 0 supplements, 33.3% used 1 supplement and 0% used 2 or more (Figure 3)

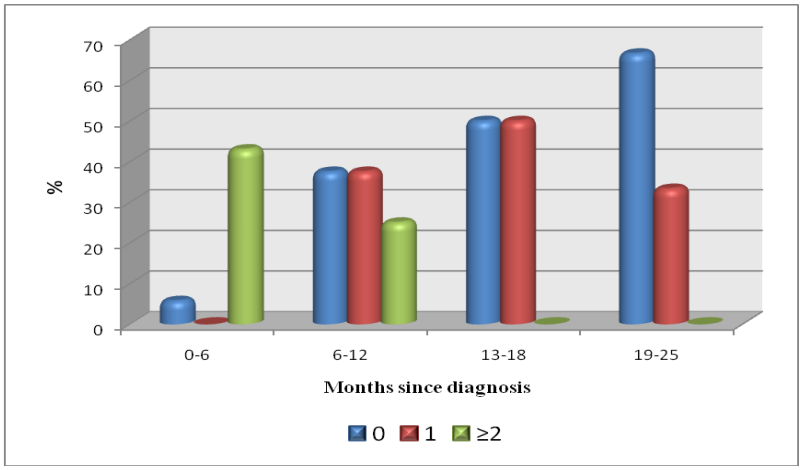

Figure 3-Prevalence of Supplement Use from Time of Diagnosis

Discussion

A previous study conducted by our team addressing biomedical interventions demonstrated that families used more supplements 2-5 years after diagnosis (Marschner, Geraghty, Guthrie, Rabidoux, Taylor). This contradiction may be due to the previous study's the use of an internet survey and how busy the families are with newly diagnosed child with ASD, rendering the population's completion of a lengthy survey nearly impossible. Receiving a phone call seemed to be a more convenient method of reaching parents with a child who has been diagnosed in the last 2 years. When studying the data regarding the number of supplements used in families with children diagnosed more than one year ago, it seems they use less supplements. However, the sample size of families with children diagnosed more than one year ago included only five participants. This is attributed to the large number of disconnected phones of families with a diagnosis more than one year ago. It is likely that families with children who have been diagnosed with

ASD move or change phone numbers more than the general population due to financial and other stresses.

One limitation of this study was the small sample size. Future studies should be conducted with a larger sample. These studies could also be improved by asking parents how they perceive the biomedical treatments are working. Several parents mentioned the perceived effectiveness in the interviews; however this data was not captured in that it was not a component of the original study objectives.

This data is clinically relevant in that demonstrated that parents are interested in biomedical treatments if their child has been diagnosed with ASD. It assists clinicians in realizing that it would be advisable to intervene shortly after diagnosis in order to reach families with evidence-based, sound information before they start their child on biomedical treatments. It is also clinically important for Occupational Therapists to understand their role in recommending treatments and practitioners. A clinician who is interested in educating parents should read Jenny McCarthy's book and browse internet sites such as Autismspeaks.com to become familiar with what information this population is consulting.

Conclusion

This study accomplished the goals of painting a broad picture of families who have had their child diagnosed in the last two years from the Ohio State University Nisonger diagnostic clinics. This picture will allow practitioners to better address the educational needs of a family with a child diagnosed with ASD. Comparing the months since diagnosis to number of supplements used, showed that families use more supplements in

the first 6 months following diagnosis and fewer supplements at 18+ months (Figure 3). Therefore, education for parents about supplement use is important in the first 6 months after diagnosis since that is when supplement use is the highest. This study also demonstrated that families are consulting a variety of allopathic and alternative practitioners as well as the internet and popular books to obtain information regarding biomedical treatments. Non-conventional practitioners composed the largest group of practitioners consulted about biomedical interventions. This is critical for a clinician to note when treating a child with ASD since not all parents are receiving the same evidence-based scientific information addressing the safety and efficacy of the various treatments. In order to best serve the ASD population, clinicians should be aware of the information parents are receiving about potentially harmful biomedical interventions and the sources of this sometimes inaccurate information, involving potentially dangerous biomedical therapies. Educational Intervention plans in the Columbus area include the development of Nutrition Interventions and Therapies for Autism (NITA) workshops for both familes and practitioners by Dr. Maureen Geraghty and her students as a service to the ever-growing autism community.

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Appendix A: Consent for Research

Verbal Consent to Conduct Interview obtained using the following Script:

This interview will take anywhere from 2-20 minutes and your participation in the study is over when the interview ends. After this simple interview, my advisor Dr. Geraghty and I will analyze the data for descriptive trends. The only foreseeable risk of participation in this study is the slim possibility of "breach of confidentiality". This risk is addressed because data will be stored in a locked drawer in a locked office where it is kept for three years then destroyed. Also identity is coded and only the principle investigator will have access to the sheet that links the codes to the identifying information. We are hoping this research will benefit the Autism community by providing data of the number of parents using biomedical treatments, the length of time between diagnosis and treatment use and how the parents become informed of these treatments. This will help clinics be aware if they need to have more professionals to consult with parents on these treatments. You may contact Jennifer Morgenstern at 317-850-6155 or Dr. Maureen Geraghty at 614-247-4595 if you have any pertinent questions about this study, the subject's rights or if you feel that there has been any research related harm. Your participation in this research is completely voluntary and refusal will not penalize you or your child in anyway. You may withdraw from this study at any time by calling the numbers given previously.

Appendix B: HIPAA Consent

Consent to use information from database was obtained using the following script:

We also need your permission to access some data from a database of Nisonger Diagnostic Team Clinic's patients. From that database we would like to look at diagnosis, date of diagnosis, age and gender. Only my advisor Dr. Geraghty and I will have access to these data if you consent We would like to compare diagnosis, date of diagnosis, age and gender to whether or not biomedical treatments are used to find any trends. Your child's PHI may be re-disclosed to the recipient and may no longer be protected by the privacy rule. Again, this is completely voluntary and you may withdraw without any negative consequences at any time.

Appendix C: Interview Script

Intro: Hi, my name is Jen Morgenstern. I am an honors student in the health and wellness major at Ohio State University and am conducting a research study for a senior thesis. The purpose of this study is to gain information on parent's uses of biomedical, or biologically based treatments such as the gluten free-casein free diet, anti-fungals, and supplements of different vitamins including B-6 and 12, magnesium, and folic acid via a telephone interview. We are also interested in where parent's gained information on these treatments. If you are interested in taking part in this study, I would need to obtain a verbal consent from you.

After consents are obtained, This is the script for the interview.

Question 1: Once you received the diagnosis, did you consider any nutrition or dietary changes, for example special diets, herbal supplements or dietary supplements?

- If the response is no: is there any reason that you came to that conclusion?
- If the response is yes: have you used any supplements or special diets
    - If yes: which diets or supplements have you used? (If the parent does not provide a list on his or her own I will prompt with a list of special diets and supplements)

Question 2: What sources have you consulted about special diets, herbal or dietary supplements?

- If the parent does not come up with a list on his or her own or if a parent only mentions one or two sources, a list of sources including friends and family, internet, workshops or health care professional will be used as a prompt
    - If internet: do you remember which sites were useful to you?
    - If health care professional: what kind of professional was it (nurse, doctor ,alternative practitioner, registered dietitian?)
    - If workshop: do you remember who sponsored the workshop?

Thank you so much for your time, I really appreciate your help!